

Appl. No. 10/615,314

Attorney Docket No. 8627-233  
(PA-5246-RFB/DIV)**II. Remarks**

Claims 40-49 have been added. Therefore, after entering this paper, claims 35, 37, and 40-49 are pending. With the remarks provided below, the Applicant respectfully requests a withdrawal and reconsideration of the rejections.

***Further Claim Clarifications***

Prior to discussing the cited references, it is believed that a brief discussion on the current form of claims 40-49 is warranted. Claims 40-49 have been added to clarify, more particularly to point out and distinctly claim that which Applicant regards as the subject matter of the present invention.

Claims 40-46 depend from claim 35 and claims 47-49 depend from claim 37. The subject matter of claims 40-42 was disclosed in the first full paragraph on page 17 of the original application as filed; the subject matter of claims 43 and 48 was disclosed in claim 2 in the original application as filed; the subject matter of claims 44 and 49 was disclosed in claim 3 in the original application as filed; the subject matter of claim 45 was disclosed in claim 12 in the original application as filed; the subject matter of claim 46 was disclosed in claim 14 in the original application as filed; and the subject matter of claim 47 was disclosed in the fourth full paragraph on page 27 of the original application as filed. Therefore, no new matter has been added.

***Rejection Under 35 U.S.C. § 103***

The Examiner rejected claims 35 and 37 under 35 U.S.C. § 103(a) as being unpatentable over *Laptewicz et al* (U.S. Patent No. 5,653,684) in view of *Gore et al* (U.S. Patent No. 5,733,400).

Claim 35 recites a catheter system having a catheter with a body portion having at least one lumen with an inside surface extending through the body portion in a longitudinal direction and at least one central member for coaxial advancement through said lumen. The body portion is made of a *multiple filament helically wound row of wires having a pitch angle in the range of 26° to 76°* and the inside surface of the body portion is mainly undeformable by the central member. (Emphasis added).

As the Examiner stated in the Office Action, *Laptewicz et al* fail to teach that the body portion of the catheter 1 is made of a multiple filament helically wound row

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of wires. (*Laptewicz et al*, Figure 1, col. 4, line 67 – col. 5, line 27). Furthermore, even if properly combinable therewith, *Gore et al* fail to cure the deficiencies of *Laptewicz et al*. For example, *Gore et al* teach a single helical reinforcement member 38 wrapped around a portion of the catheter body 14 rather than *multiple* filament wires as recited in claim 35. (*Gore et al*, Figure 1, col. 5, lines 10-20). As an example of multiple filaments helically wound into a row of wires, Figure 7 in the original application as filed shows four filaments 5 being simultaneously wound around a mandrel 7 during an exemplary method of forming a catheter. Therefore, the multiple filament helically wound row of wires recited in claim 35 is not rendered obvious by the combination of *Gore et al* and *Laptewicz et al*.

As another example, the combination of *Laptewicz et al* and *Gore et al* fails to render obvious a row of wires having a pitch angle in the range of 26° to 76° as recited in claim 35. The Examiner states that it would be obvious to modify the helical reinforcement member 38 in *Gore et al* to have a pitch angle in the range of 26° to 76° since discovering the optimum or workable ranges involves only routine skill in the art. However, as specified in MPEP § 2144.05 (II)(B), a particular parameter must first be recognized as a result-effective variable, i.e. a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable). Neither *Gore et al* nor *Laptewicz et al* disclose the pitch angle of the reinforcement member 38 as being a result-effective variable. In fact, the only mention of pitch angle in either reference is in *Gore et al* when it states that the pitch increases in the second helical portion of the reinforcement member 38 to be able to have spacing between the respective coils 44. (*Gore et al*, col. 5, lines 53-60). Neither reference discusses or identifies any advantages or results of modification of the reinforcement member 38 pitch angle. Therefore, the pitch angle of the row of wires recited in claim 35 is not a result-effective variable and the combination of *Gore et al* and *Laptewicz et al*, even if proper, fails to render obvious claim 35.

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Therefore, Applicant asserts that claim 35 is allowable and such action is requested.

Claim 37 recites a delivery system having a delivery device with a shaft portion having at least one lumen, a *self-expandable prosthesis*, and a pusher member arranged in the lumen of said delivery device to cause relative axial movement of the self-expandable prosthesis. The shaft portion includes a helically wound *multiple filament row of wires*. (Emphasis added).

As the Examiner stated in the Office Action, *Laptewicz et al* fail to teach that the body portion of the catheter 1 is made of a multiple filament helically wound row of wires. (*Laptewicz et al*, Figure 1, col. 4, line 67 – col. 5, line 27). Furthermore, even if properly combinable therewith, *Gore et al* fail to cure the deficiencies of *Laptewicz et al*. For example, *Gore et al* teach a single helical reinforcement member 38 wrapped around a portion of the catheter body 14 rather than *multiple* filament wires as recited in claim 37. (*Gore et al*, Figure 1, col. 5, lines 10-20). As an example of multiple filaments helically wound into a row or wires, Figure 7 in the original application as filed shows four filaments 5 being simultaneously wound around a mandrel 7 during an exemplary method of forming a catheter. Therefore, the multiple filaments helically wound row of wires recited in claim 37 is not rendered obvious by the combination of *Gore et al* and *Laptewicz et al*.

As another example, the combination of *Laptewicz et al* and *Gore et al* fails to render obvious a *self-expandable prosthesis* as recited in claim 37.

Therefore, Applicant asserts that claim 37 is allowable and such action is requested.

### Conclusion

In view of the above amendments and remarks, it is respectfully submitted that the present form of the claims are patentably distinguishable over the art of record and that this application is now in condition for allowance. The Examiner is

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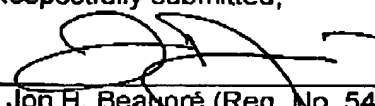
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invited to contact the undersigned attorney for the Applicant's via telephone number (734) 302-6000, if such communication would expedite this application.

Respectfully submitted,

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Date

  
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